

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BIOGEN INTERNATIONAL GMBH)	
and BIOGEN MA INC.,)	
)	
Plaintiffs,)	
)	C.A. No. 17-823-LPS
v.)	(Consolidated)
)	
AMNEAL PHARMACEUTICALS LLC,)	C.A. No. 17-845-LPS
)	
Defendant.)	
_____)	

STIPULATION OF INFRINGEMENT BY MSN

WHEREAS Plaintiffs Biogen International GmbH and Biogen MA Inc. (collectively, “Biogen”) assert that Defendants MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc. (collectively, “MSN”) infringe claims 1-4, 6, 8-13, 15, and 16 of U.S. Patent No. 8,399,514 (“the ’514 patent”) (collectively, the “Asserted Claims” of the “Asserted Patent”) by submitting, or causing to be submitted, Abbreviated New Drug Application No. 210460 (“MSN’s ANDA”) seeking approval to engage in the commercial manufacture, use, import, sale, or offer to sell MSN’s generic capsules containing dimethyl fumarate (“MSN’s ANDA Products”), which if approved and marketed, will infringe the Asserted Claims;

WHEREAS claims 5, 7, 14, and 17-20 of the ’514 patent have not been asserted;

WHEREAS, MSN’s ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in its opinion, the Asserted Patent is invalid, unenforceable, or would not be infringed by the commercial manufacture, use, or sale of MSN’s ANDA Products;

WHEREAS, MSN denies that the commercial marketing and sale of MSN’s ANDA Products would infringe any valid and enforceable claims asserted in this case but desires to streamline the issues at trial;

NOW THEREFORE, Biogen and MSN, by their undersigned counsel, STIPULATE as follows:

1. For purposes of this Action only, MSN stipulates that its submission of ANDA No. 210460 constitutes infringement of the Asserted Claims pursuant to 35 U.S.C. § 271(e)(2)(A), provided those claims are not proven invalid or unenforceable. MSN further stipulates that the commercial manufacture, use, sale, offer to sell, and/or importation of MSN's ANDA Products prior to the expiration of the Asserted Patent in accordance with the labeling proposed in MSN's ANDA No. 210460 would further infringe the Asserted Claims pursuant to 35 U.S.C. § 271, provided those claims are not proven invalid or unenforceable.
2. By entering into this Stipulation, MSN does not waive any invalidity defenses it has raised. This Stipulation shall not be used to argue that claims satisfy the definiteness requirements of 35 U.S.C. § 112, or for any other purpose other than the issue of infringement. This Stipulation may not be used or admitted in any proceeding other than the instant proceeding against MSN concerning ANDA No. 210460.
3. The parties reserve all other claims and defenses.

IT IS HEREBY STIPULATED:

Dated: October 24, 2019

ASHBY & GEDDES

/s/ Steven J. Balick

Steven J. Balick (#2114)
Andrew C. Mayo (#5207)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, DE 19899
(302) 654-1888
sbalick@ashbygeddes.com
amayo@ashbygeddes.com

Attorneys for Plaintiffs

PHILLIPS, GOLDMAN, MCCLAUGHLIN &
HALL, P.A.

/s/ John C. Phillips, Jr.

John C. Phillips, Jr.
David A. Bilson
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pgmhlaw.com
dab@pgmhlaw.com

*Attorneys for Defendants MSN Laboratories
Private Ltd. and MSN Pharmaceuticals Inc.*

SO ORDERED, this _____ day of _____, 2019

Chief Judge